

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Nancy Smyth-Templeton, et al.
Application No.: - **Group No.:** 1615 (presumed)
Filed: Herewith **Examiner:** G. Kishore (presumed)
For: NOVELL LIPOSOME COMPLEXES FOR INCREASED
SYSTEMIC DELIVERY

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV438992045US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 15, 2004.

By: _____

Donna R. Davis

MAIL STOP PATENT APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.

Customer No.: 21874
Attorney Docket No.: 60251-CON2(47992)
U.S. Serial No.: -
Filing Date: Herewith
Group Art Unit: 1615 (presumed)
Examiner: G. Kishore (presumed)

II. COPIES

- a. ☐ Submitted herewith is a legible copy of (i) each U.S and foreign patent; (ii) each publication or that portion which caused it to be listed; and (iii) all other information or that portion which caused it to be listed.
- b. ☒ This application relies, under 35 U.S.C. § 120, on the earlier filing date of prior application **Serial No. 09/991,028**, filed on **November 20, 2001** and Serial No. **09/242,190**, filed on **October 4, 1999**. The following references were submitted to, and/or cited by, the Office in the prior application (s) and, therefore, are not required to be provided in this application.

III. CONCISE EXPLANATION OF THE RELEVANCE

(check at least one box)

- a. ☒ Except as may be indicated below in (b), all of the patents, publications or other information are in the English language or were cited in an English language Search Report, a copy of which is attached hereto (concise explanation not required).
- b. ☐ A concise explanation of the relevance of all patents, publications or other information listed that is not in the English language is as follows:
- c. ☐ The following additional information is provided for the Examiner's consideration:

FEES

IV. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(b)

(check one box)

- a. ☒ within three months of the filing date of a national application (37 C.F.R. § 1.97(b) (1). No fee or certification is required.
- b. ☐ within three months of the date of entry of the national stage as set forth in §1.491 in an international application (37 C.F.R. § 1.97(b) (2). No fee or certification is required.

Customer No.: 21874
Attorney Docket No.: 60251-CON2(47992)
U.S. Serial No.: -
Filing Date: Herewith
Group Art Unit: 1615 (presumed)
Examiner: G. Kishore (presumed)

- c. ☐ Before the mailing date of a first Action on the merits (37 C.F.R. § 1.97(b) (3)). No fee or certification is required. In the event that a first Office Action on the merits has been issued, please consider this IDS under 37 C.F.R. § 1.97(c) and see the certification under 37 C.F.R. § 1.97(e) below, or, if no certification has been made, charge our deposit account a fee in the amount of \$180.00 as required by 37 C.F.R. § 1.17(p).

V. THIS IDS IS BEING FILED UNDER 37 C.F.R. § 1.97(c):
(check one box)

before the mailing date of a Final Office Action under 37 C.F.R. § 1.113 (See 37 C.F.R. § 1.97(c) (1)) or before the mailing date of a Notice of Allowance under 37 C.F.R. § 1.311 (See 37 C.F.R. § 1.97(c) (2)).

- a. ☐ No certification; therefore, a fee in the amount of \$180.00 is required by 37 C.F.R. § 1.17(p).
or
b. ☐ See the certification below. No fee is required.

VI. STATEMENT UNDER 37 C.F.R. § 1.97(e) (check only one box)

The undersigned hereby states that

- a. ☐ each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS; or
b. ☐ no item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

Customer No.: 21874
Attorney Docket No.: 60251-CON2(47992)
U.S. Serial No.: -
Filing Date: Herewith
Group Art Unit: 1615 (presumed)
Examiner: G. Kishore (presumed)

c. ☐ Some of the items of information were cited in a communication from a foreign Patent Office. As to this information, the undersigned certifies that each item of information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application not more than three months prior to the filing of this IDS. As to the remaining information, the undersigned hereby certifies that no item of this remaining information contained in the IDS was cited in a communication from a foreign Patent Office in a counterpart foreign application or, to the best of my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this statement.

☐ Please charge Deposit Account No. 04-1105 in the amount of \$180.00 for the above-indicated fee. A triplicate copy of this paper is attached.

☒ No fee is required.

If the Examiner has any questions concerning this IDS, he/she is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the PTO is requested to consider this IDS under the proper rule, with a petition if necessary, and charge the appropriate fee to Deposit Account No. **04-1105**.

Respectfully submitted,

Date: April 15, 2004

By: 

Gregory B. Butler, Ph.D., Esq.
Reg. No.: 34,558
Attorney for Applicant(s)

EDWARDS & ANGELL, LLP
P. O. Box 55874
Boston, MA 02205
Tel: (617) 439-4444
Fax: (617) 439-4170
Customer No.: 21874

FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT		DOCKET NO.: 60251-CON2(47992)		SERIAL NO.: -			
		APPLICANT(S): N. Smyth-Templeton, et al.					
		FILING DATE: Herewith		GROUP NO.: 1615 (presumed)			
UNITED STATES PATENT DOCUMENTS							
EXAM. INITIALS		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE
	AA	5,580,859	12/1996	Felgner			
	AB	5,827,703	10/1998	Debs			
	AC	5,206,027	4/1993	Kitaguchi			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION YES/NO
	BA	WO 93/25673	23.12.1993	PCT			
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)							
	CA	B. Sternberg, "Morphology of Cationic Liposome/DNA Complexes in Relation to Their Chemical Compositions," <i>Journal of Liposome Research</i> , 6(3), pp 515-533 (1996).					
	CB	T. Kato, et al., "Synthetic Cationic Amphiphile for Liposome-Mediated DNA Transfection with Less Cytotoxicity," <i>Biol. Pharm. Bull.</i> , 19(6), pp. 860-863 (1996).					
	CC	E. K. Wassan, et al., "Plasmid DNA is Protected Against Ultrasonic Cavitation-Induced Damage When Complexed to Cationic Liposomes," <i>Journal Pharm. Sciences</i> , 85(4), pp. 427-433 (1996).					
EXAMINER:					DATE:		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Nancy Smyth-Templeton, et al.
Application No.: - **Group No.:** 1615 (presumed)
Filed: Herewith **Examiner:** G. Kishore (presumed)
For: NOVELL LIPOSOME COMPLEXES FOR INCREASED
SYSTEMIC DELIVERY

CERTIFICATE OF EXPRESS MAIL

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service in an envelope as "Express Mail Post Office to Addressee," Express Mail Label No. **EV438992045US** addressed to: **MAIL STOP PATENT APPLICATION**, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on April 10, 2004.

By: _____

Donna R. Davis

MAIL STOP PATENT APPLICATION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Dear Sir:

Pursuant to 37 C.F.R. §§ 1.97 and 1.98, applicant(s) hereby submit(s) an Information Disclosure Statement for consideration by the Examiner.

I. **LIST OF PATENTS, PUBLICATIONS OR OTHER INFORMATION**

The patents, publications or other information submitted for consideration by the Office are listed on PTO-1449, attached hereto.